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Shire LLC and Shire Development, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SHIRE LLC and SHIRE DEVELOPMENT INC. Plaintiffs, v. ACTAVIS ELIZABETH LLC and ACTAVIS INC. Defendants.	C.A. No. _____ ***Document electronically filed.***

COMPLAINT

Plaintiffs Shire LLC and Shire Development Inc. (collectively "Shire"), by its undersigned attorneys, for its Complaint against defendants Actavis Elizabeth LLC and Actavis Inc. (collectively, "Actavis") herein, allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent No. 7,105,486 ("the '486 patent") (attached as Exhibit A hereto); United States Patent No. 7,223,735 ("the '735 patent") (attached as Exhibit B hereto); United States Patent No. 7,655,630 ("the '630 patent") (attached as Exhibit C hereto); United States Patent No. 7,659,253 ("the '253 patent") (attached as Exhibit D hereto); United States Patent No. 7,659,254 ("the '254 patent") (attached as Exhibit E hereto); United States Patent No. 7,662,787 ("the '787 patent") (attached as Exhibit F hereto); United States Patent No. 7,671,030 ("the '030 patent") (attached as Exhibit G hereto); United States Patent No. 7,671,031 ("the '031 patent") (attached as Exhibit H hereto); United States Patent No. 7,674,774 ("the '774 patent") (attached as Exhibit I hereto); United States Patent No. 7,678,770 ("the '770 patent") (attached as Exhibit J hereto); United States Patent No. 7,678,771 ("the '771 patent") (attached as Exhibit K hereto); United States Patent No. 7,687,466 ("the '466 patent") (attached as Exhibit L hereto); United States Patent No. 7,687,467 ("the '467 patent") (attached as Exhibit M hereto); United States Patent No. 7,700,561 ("the '561 patent") (attached as Exhibit N hereto); United States Patent No. 7,718,619 ("the '619 patent") (attached as Exhibit O hereto); and United States Patent No. 7,723,305 ("the '305 patent") (attached as Exhibit P hereto).

THE PARTIES

2. Plaintiff Shire LLC is a corporation organized and existing under the laws of the State of Kentucky, having a place of business at 9200 Brookfield Court, Florence, Kentucky 41042.

3. Plaintiff Shire Development Inc. is a corporation organized and existing

under the laws of the State of Delaware, having a place of business at 725 Chesterbrook Boulevard, Wayne, Pennsylvania 19087.

4. Upon information and belief, Actavis Elizabeth LLC is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07202.

5. Upon information and belief, Actavis Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960.

6. Upon information and belief, Actavis Elizabeth LLC is a wholly-owned subsidiary of Actavis Inc.

7. Upon information and belief, Actavis Elizabeth LLC acts at the direction of, under the control of, and for the direct benefit of Actavis Inc. and is controlled and/or dominated by Actavis Inc.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Actavis. Actavis has submitted to personal jurisdiction in this Court because, inter alia, it resides, and is doing business in New Jersey.

10. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

FACTS AS TO ALL COUNTS

11. Shire Development Inc. is the owner of New Drug Application ("NDA") No. 021977, which was approved by the FDA for the manufacture and sale of Vyvanse®.

Vyvanse® is the trade name for lisdexamfetamine dimesylate, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, and 70 mg capsules for oral administration and is approved for the treatment of Attention Deficit Hyperactivity Disorder ("ADHD").

12. Pursuant to 21 U.S.C. § 355(b)(1), the '486 patent, the '735 patent, the '630 patent, the '253 patent, the '254 patent, the '787 patent, the '030 patent, the '031 patent, the '774 patent, the '770 patent, the '771 patent, the '466 patent, the '467 patent, the '561 patent, the '619 patent, and the '305 patent ("the Patents-in-Suit") are listed in FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "*Orange Book*") as covering the Vyvanse® product.

13. Shire LLC has been assigned, and currently owns, the rights to each of the Patents-in-Suit.

14. The '486 patent, titled "Abuse-Resistant Amphetamine Compounds," was duly and legally issued on September 12, 2006. The '486 patent is generally directed to methods of treatment using L-lysine-d-amphetamine

15. The '735 patent, titled "Abuse Resistant Lysine Amphetamine Compounds," was duly and legally issued on May 29, 2007. The '735 patent is generally directed to pharmaceutical compositions comprising L-lysine-d-amphetamine.

16. The '630 patent, titled "Abuse-Resistant Amphetamine Prodrugs," was duly and legally issued on February 2, 2010. The '630 patent is generally directed to the compound, L-lysine-d-amphetamine dimesylate.

17. The '253 patent, titled "Abuse-Resistant Amphetamine Prodrugs," was duly and legally issued on February 9, 2010. The '253 patent is generally directed to crystalline lisdexamphetamine dimesylate.

18. The '254 patent, titled "Abuse-Resistant Amphetamine Prodrugs," was duly and legally issued on February 9, 2010. The '254 patent is generally directed to methods of treatment comprising L-lysine-d-amphetamine.

19. The '787 patent, titled "Abuse Resistant Lysine Amphetamine Compounds" was duly and legally issued on February 16, 2010. The '787 patent is generally directed to L-lysine-d-amphetamine compounds.

20. The '030 patent, titled "Abuse-Resistant Amphetamine Prodrugs" was duly and legally issued on March 2, 2010. The '030 patent is generally directed to compositions comprising L-lysine-d-amphetamine .

21. The '031 patent, titled "Abuse-Resistant Amphetamine Prodrugs" was duly and legally issued on March 2, 2010. The '031 patent is generally directed to methods of delivering amphetamines.

22. The '774 patent, titled "Abuse-Resistant Amphetamine Prodrugs" was duly and legally issued on March 9, 2010. The '774 patent is generally directed to compositions comprising L-lysine-d-amphetamine.

23. The '770 patent, titled "Abuse-Resistant Amphetamine Prodrugs" was duly and legally issued on March 16, 2010. The '770 patent is generally directed to methods of treatment comprising L-lysine-d-amphetamine.

24. The '771 patent, titled "Abuse-Resistant Amphetamine Prodrugs" was duly and legally issued on March 16, 2010. The '771 patent is generally directed to compositions comprising L-lysine-d-amphetamine.

25. The '466 patent, titled "Abuse-Resistant Amphetamine Prodrugs" was duly and legally issued on March 30, 2010. The '466 patent is generally directed to

compositions comprising L-lysine-d-amphetamine.

26. The '467 patent, titled "Abuse-Resistant Amphetamine Prodrugs" was duly and legally issued on March 30, 2010. The '467 patent is generally directed to compositions comprising L-lysine-d-amphetamine.

27. The '561 patent, titled "Abuse-Resistant Amphetamine Prodrugs" was duly and legally issued on April 20, 2010. The '561 patent is generally directed to compositions comprising L-lysine-d-amphetamine.

28. The '619 patent, titled "Abuse-Resistant Amphetamine Prodrugs" was duly and legally issued on May 18, 2010. The '619 patent is generally directed to compositions comprising L-lysine-d-amphetamine.

29. The '305 patent, titled "Abuse-Resistant Amphetamine Prodrugs" was duly and legally issued on May 25, 2010. The '305 patent is generally directed to compositions comprising L-lysine-d-amphetamine.

30. Upon information and belief, Actavis Inc. and Actavis Elizabeth LLC worked in concert to prepare, submit, and file Abbreviated New Drug Application ("ANDA") No. 202802 ("the Actavis ANDA") to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of generic lisdexamfetamine dimesylate capsules, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, and 70 mg, for oral administration ("the Actavis Proposed Product").

31. Actavis sent a letter to Shire Pharmaceuticals, Inc. and Shire LLC purporting to provide notification that the Actavis ANDA contains certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification") with regard to the '486

patent, the '735 patent, the '630 patent, the '253 patent, the '254 patent, the '787 patent, the '030 patent, the '031 patent, the '774 patent, the '770 patent, the '771 patent, the '466 patent, the '467 patent, the '561 patent, the '619 patent, and the '305 patent ("the Actavis Notice Letter").

32. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires a paragraph IV notification to include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. §§ 314.95(c)(6)(i)-(ii).

33. The Actavis Notice Letter does not assert non-infringement for each and every claim of each and every patent for which Actavis has made a paragraph IV certification.

34. The Actavis Notice Letter does not provide a full and detailed explanation of Actavis's factual and legal basis of invalidity and/or unenforceability for each and every claim of each and every patent for which Actavis has made a paragraph IV certification.

35. Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III), the Actavis Notice Letter contained an Offer of Confidential Access to the Actavis ANDA. Shire requested a copy of the Actavis ANDA and samples of the Actavis Proposed Product from Actavis. Actavis has not produced the Actavis ANDA or any samples of Actavis Proposed Product.

FIRST COUNT
(Infringement of the '486 Patent by Actavis)

36. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

37. Upon information and belief, Actavis seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Actavis Proposed Product.

38. Upon information and belief, Actavis included a paragraph IV certification to the '486 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '486 patent.

39. Upon information and belief, Actavis will commercially manufacture, sell, offer for sale, and/or import the Actavis Proposed Product upon FDA approval.

40. Upon information and belief, as of the date of the Actavis Notice Letter, Actavis was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

41. The inclusion of a paragraph IV certification to the '486 patent in ANDA No. 202802 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '486 patent is an act of infringement by Actavis of one or more claims of the '486 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

42. Upon information and belief, Actavis's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Actavis Proposed Product that is the subject of ANDA No. 202802 will infringe one or more claims of the '486 patent

under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

43. Upon information and belief, Actavis is aware of the existence of the '486 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '486 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

44. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Actavis is preliminarily and permanently enjoined by this Court.

SECOND COUNT
(Infringement of the '735 Patent by Actavis)

45. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

46. Upon information and belief, Actavis seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Actavis Proposed Product.

47. Upon information and belief, Actavis included a paragraph IV certification to the '735 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '735 patent.

48. Upon information and belief, Actavis will commercially manufacture, sell, offer for sale, and/or import the Actavis Proposed Product upon FDA approval.

49. Upon information and belief, as of the date of the Actavis Notice Letter, Actavis was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

50. The inclusion of a paragraph IV certification to the '735 patent in ANDA No. 202802 for the purpose of obtaining approval to engage in the commercial manufacture,

use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '735 patent is an act of infringement by Actavis of one or more claims of the '735 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

51. Upon information and belief, Actavis's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Actavis Proposed Product that is the subject of ANDA No. 202802 will infringe one or more claims of the '735 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

52. Upon information and belief, Actavis is aware of the existence of the '735 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '735 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

53. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Actavis is preliminarily and permanently enjoined by this Court.

THIRD COUNT
(Infringement of the '630 Patent by Actavis)

54. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

55. Upon information and belief, Actavis seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Actavis Proposed Product.

56. Upon information and belief, Actavis included a paragraph IV certification to the '630 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '630 patent.

57. Upon information and belief, Actavis will commercially manufacture, sell, offer for sale, and/or import the Actavis Proposed Product upon FDA approval.

58. Upon information and belief, as of the date of the Actavis Notice Letter, Actavis was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

59. The inclusion of a paragraph IV certification to the '630 patent in ANDA No. 202802 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '630 patent is an act of infringement by Actavis of one or more claims of the '630 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

60. Upon information and belief, Actavis's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Actavis Proposed Product that is the subject of ANDA No. 202802 will infringe one or more claims of the '630 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

61. Upon information and belief, Actavis is aware of the existence of the '630 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '630 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

62. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Actavis is preliminarily and permanently enjoined by this Court.

FOURTH COUNT
(Infringement of the '253 Patent by Actavis)

63. Shire repeats and realleges each of the foregoing paragraphs as if fully set

forth herein.

64. Upon information and belief, Actavis seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Actavis Proposed Product.

65. Upon information and belief, Actavis included a paragraph IV certification to the '253 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '253 patent.

66. Upon information and belief, Actavis will commercially manufacture, sell, offer for sale, and/or import the Actavis Proposed Product upon FDA approval.

67. Upon information and belief, as of the date of the Actavis Notice Letter, Actavis was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

68. The inclusion of a paragraph IV certification to the '253 patent in ANDA No. 202802 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '253 patent is an act of infringement by Actavis of one or more claims of the '253 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

69. Upon information and belief, Actavis's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Actavis Proposed Product that is the subject of ANDA No. 202802 will infringe one or more claims of the '253 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

70. Upon information and belief, Actavis is aware of the existence of the '253

patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '253 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

71. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Actavis is preliminarily and permanently enjoined by this Court.

FIFTH COUNT
(Infringement of the '254 Patent by Actavis)

72. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

73. Upon information and belief, Actavis seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Actavis Proposed Product.

74. Upon information and belief, Actavis included a paragraph IV certification to the '254 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '254 patent.

75. Upon information and belief, Actavis will commercially manufacture, sell, offer for sale, and/or import the Actavis Proposed Product upon FDA approval.

76. Upon information and belief, as of the date of the Actavis Notice Letter, Actavis was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

77. The inclusion of a paragraph IV certification to the '254 patent in ANDA No. 202802 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '254 patent is an act of infringement by Actavis of one or more claims of the

'254 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

78. Upon information and belief, Actavis's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Actavis Proposed Product that is the subject of ANDA No. 202802 will infringe one or more claims of the '254 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

79. Upon information and belief, Actavis is aware of the existence of the '254 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '254 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

80. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Actavis is preliminarily and permanently enjoined by this Court.

SIXTH COUNT
(Infringement of the '787 Patent by Actavis)

81. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

82. Upon information and belief, Actavis seeks FDA approval for the manufacture, marketing, sale and/or distribution of the Actavis Proposed Product.

83. Upon information and belief, Actavis included a paragraph IV certification to the '787 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '787 patent.

84. Upon information and belief, Actavis will commercially manufacture, sell, offer for sale, and/or import the Actavis Proposed Product upon FDA approval.

85. Upon information and belief, as of the date of the Actavis Notice Letter, Actavis was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

86. The inclusion of a paragraph IV certification to the '787 patent in ANDA No. 202802 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '787 patent is an act of infringement by Actavis of one or more claims of the '787 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

87. Upon information and belief, Actavis's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Actavis Proposed Product that is the subject of ANDA No. 202802 will infringe one or more claims of the '787 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

88. Upon information and belief, Actavis is aware of the existence of the '787 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '787 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

89. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Actavis is preliminarily and permanently enjoined by this Court.

SEVENTH COUNT
(Infringement of the '030 Patent by Actavis)

90. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

91. Upon information and belief, Actavis seeks FDA approval for the

manufacture, marketing, sale, and/or distribution of the Actavis Proposed Product.

92. Upon information and belief, Actavis included a paragraph IV certification to the '030 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '030 patent.

93. Upon information and belief, Actavis will commercially manufacture, sell, offer for sale, and/or import the Actavis Proposed Product upon FDA approval.

94. Upon information and belief, as of the date of the Actavis Notice Letter, Actavis was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

95. The inclusion of a paragraph IV certification to the '030 patent in ANDA No. 202802 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '030 patent is an act of infringement by Actavis of one or more claims of the '030 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

96. Upon information and belief, Actavis's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Actavis Proposed Product that is the subject of ANDA No. 202802 will infringe one or more claims of the '030 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

97. Upon information and belief, Actavis is aware of the existence of the '030 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '030 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

98. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Actavis is preliminarily and permanently enjoined by this Court.

EIGHTH COUNT
(Infringement of the '031 Patent by Actavis)

99. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

100. Upon information and belief, Actavis seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Actavis Proposed Product.

101. Upon information and belief, Actavis included a paragraph IV certification to the '031 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '031 patent.

102. Upon information and belief, Actavis will commercially manufacture, sell, offer for sale, and/or import the Actavis Proposed Product upon FDA approval.

103. Upon information and belief, as of the date of the Actavis Notice Letter, Actavis was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

104. The inclusion of a paragraph IV certification to the '031 patent in ANDA No. 202802 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '031 patent is an act of infringement by Actavis of one or more claims of the '031 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

105. Upon information and belief, Actavis's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Actavis Proposed Product that is the subject of ANDA No. 202802 will infringe one or more claims of the '031 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

106. Upon information and belief, Actavis is aware of the existence of the '031 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '031 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

107. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Actavis is preliminarily and permanently enjoined by this Court.

NINTH COUNT
(Infringement of the '774 Patent by Actavis)

108. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

109. Upon information and belief, Actavis seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Actavis Proposed Product.

110. Upon information and belief, Actavis included a paragraph IV certification to the '774 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '774 patent.

111. Upon information and belief, Actavis will commercially manufacture, sell, offer for sale, and/or import the Actavis Proposed Product upon FDA approval.

112. Upon information and belief, as of the date of the Actavis Notice Letter, Actavis was aware of the statutory provisions and regulations set forth in

21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

113. The inclusion of a paragraph IV certification to the '774 patent in ANDA No. 202802 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '774 patent is an act of infringement by Actavis of one or more claims of the '774 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

114. Upon information and belief, Actavis's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Actavis Proposed Product that is the subject of ANDA No. 202802 will infringe one or more claims of the '774 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

115. Upon information and belief, Actavis is aware of the existence of the '774 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '774 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

116. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Actavis is preliminarily and permanently enjoined by this Court.

TENTH COUNT
(Infringement of the '770 Patent by Actavis)

117. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

118. Upon information and belief, Actavis seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Actavis Proposed Product.

119. Upon information and belief, Actavis included a paragraph IV

certification to the '770 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '770 patent.

120. Upon information and belief, Actavis will commercially manufacture, sell, offer for sale, and/or import the Actavis Proposed Product upon FDA approval.

121. Upon information and belief, as of the date of the Actavis Notice Letter, Actavis was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

122. The inclusion of a paragraph IV certification to the '770 patent in ANDA No. 202802 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '770 patent is an act of infringement by Actavis of one or more claims of the '770 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

123. Upon information and belief, Actavis's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Actavis Proposed Product that is the subject of ANDA No. 202802 will infringe one or more claims of the '770 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

124. Upon information and belief, Actavis is aware of the existence of the '770 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '770 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

125. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Actavis is preliminarily and

permanently enjoined by this Court.

ELEVENTH COUNT
(Infringement of the '771 Patent by Actavis)

126. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

127. Upon information and belief, Actavis seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Actavis Proposed Product.

128. Upon information and belief, Actavis included a paragraph IV certification to the '771 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '771 patent.

129. Upon information and belief, Actavis will commercially manufacture, sell, offer for sale, and/or import the Actavis Proposed Product upon FDA approval.

130. Upon information and belief, as of the date of the Actavis Notice Letter, Actavis was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

131. The inclusion of a paragraph IV certification to the '771 patent in ANDA No. 202802 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '771 patent is an act of infringement by Actavis of one or more claims of the '771 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

132. Upon information and belief, Actavis's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Actavis Proposed Product

that is the subject of ANDA No. 202802 will infringe one or more claims of the '771 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

133. Upon information and belief, Actavis is aware of the existence of the '771 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '771 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

134. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Actavis is preliminarily and permanently enjoined by this Court.

TWELFTH COUNT
(Infringement of the '466 Patent by Actavis)

135. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

136. Upon information and belief, Actavis seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Actavis Proposed Product.

137. Upon information and belief, Actavis included a paragraph IV certification to the '466 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '466 patent.

138. Upon information and belief, Actavis will commercially manufacture, sell, offer for sale, and/or import the Actavis Proposed Product upon FDA approval.

139. Upon information and belief, as of the date of the Actavis Notice Letter, Actavis was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

140. The inclusion of a paragraph IV certification to the '466 patent in ANDA

No. 202802 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '466 patent is an act of infringement by Actavis of one or more claims of the '466 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

141. Upon information and belief, Actavis's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Actavis Proposed Product that is the subject of ANDA No. 202802 will infringe one or more claims of the '466 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

142. Upon information and belief, Actavis is aware of the existence of the '466 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '466 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

143. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Actavis is preliminarily and permanently enjoined by this Court.

THIRTEENTH COUNT
(Infringement of the '467 Patent by Actavis)

144. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

145. Upon information and belief, Actavis seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Actavis Proposed Product.

146. Upon information and belief, Actavis included a paragraph IV certification to the '467 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the

expiration of the '467 patent.

147. Upon information and belief, Actavis will commercially manufacture, sell, offer for sale, and/or import the Actavis Proposed Product upon FDA approval.

148. Upon information and belief, as of the date of the Actavis Notice Letter, Actavis was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

149. The inclusion of a paragraph IV certification to the '467 patent in ANDA No. 202802 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '467 patent is an act of infringement by Actavis of one or more claims of the '467 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

150. Upon information and belief, Actavis's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Actavis Proposed Product that is the subject of ANDA No. 202802 will infringe one or more claims of the '467 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

151. Upon information and belief, Actavis is aware of the existence of the '467 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '467 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

152. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Actavis is preliminarily and permanently enjoined by this Court.

FOURTEENTH COUNT
(Infringement of the '561 Patent by Actavis)

153. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

154. Upon information and belief, Actavis seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Actavis Proposed Product.

155. Upon information and belief, Actavis included a paragraph IV certification to the '561 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '561 patent.

156. Upon information and belief, Actavis will commercially manufacture, sell, offer for sale, and/or import the Actavis Proposed Product upon FDA approval.

157. Upon information and belief, as of the date of the Actavis Notice Letter, Actavis was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

158. The inclusion of a paragraph IV certification to the '561 patent in ANDA No. 202802 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '561 patent is an act of infringement by Actavis of one or more claims of the '561 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

159. Upon information and belief, Actavis's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Actavis Proposed Product that is the subject of ANDA No. 202802 will infringe one or more claims of the '561 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

160. Upon information and belief, Actavis is aware of the existence of the '561 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '561 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

161. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Actavis is preliminarily and permanently enjoined by this Court.

FIFTEENTH COUNT
(Infringement of the '619 Patent by Actavis)

162. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

163. Upon information and belief, Actavis seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Actavis Proposed Product.

164. Upon information and belief, Actavis included a paragraph IV certification to the '619 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '619 patent.

165. Upon information and belief, Actavis will commercially manufacture, sell, offer for sale, and/or import the Actavis Proposed Product upon FDA approval.

166. Upon information and belief, as of the date of the Actavis Notice Letter, Actavis was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

167. The inclusion of a paragraph IV certification to the '619 patent in ANDA No. 202802 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the

expiration of the '619 patent is an act of infringement by Actavis of one or more claims of the '619 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

168. Upon information and belief, Actavis's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Actavis Proposed Product that is the subject of ANDA No. 202802 will infringe one or more claims of the '619 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

169. Upon information and belief, Actavis is aware of the existence of the '619 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '619 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

170. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Actavis is preliminarily and permanently enjoined by this Court.

SIXTEENTH COUNT
(Infringement of the '305 Patent by Actavis)

171. Shire repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

172. Upon information and belief, Actavis seeks FDA approval for the manufacture, marketing, sale, and/or distribution of the Actavis Proposed Product.

173. Upon information and belief, Actavis included a paragraph IV certification to the '305 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '305 patent.

174. Upon information and belief, Actavis will commercially manufacture,

sell, offer for sale, and/or import the Actavis Proposed Product upon FDA approval.

175. Upon information and belief, as of the date of the Actavis Notice Letter, Actavis was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

176. The inclusion of a paragraph IV certification to the '305 patent in ANDA No. 202802 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Actavis Proposed Product before the expiration of the '305 patent is an act of infringement by Actavis of one or more claims of the '305 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

177. Upon information and belief, Actavis's commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Actavis Proposed Product that is the subject of ANDA No. 202802 will infringe one or more claims of the '305 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

178. Upon information and belief, Actavis is aware of the existence of the '305 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '305 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

179. The acts of infringement set forth above will cause Shire irreparable harm for which it has no adequate remedy at law, unless Actavis is preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests the following relief:

i. A judgment declaring that the '486 patent is valid and enforceable;

ii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202802 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 was an act of infringement of the '486 patent by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

iii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 prior to the expiration of the '486 patent, including any regulatory extensions, will constitute an act of infringement by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

iv. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202802 shall be no earlier than the date on which the '486 patent expires including any regulatory extensions;

v. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Actavis and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 until the expiration of the '486 patent including any regulatory extensions;

vi. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Actavis commercially manufactures, uses, sells, offers to sell

and/or imports any product that is the subject of ANDA No. 202802 that infringes the '486 patent;

vii. A judgment declaring that infringement of the '486 patent is willful if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '486 patent;

viii. A judgment declaring that the '735 patent is valid and enforceable;

ix. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202802 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 was an act of infringement of the '735 patent by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

x. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 prior to the expiration of the '735 patent, including any regulatory extensions, will constitute an act of infringement by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

xi. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202802 shall be no earlier than the date on which the '735 patent expires including any regulatory extensions;

xii. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Actavis and their officers, agents, servants, employees and attorneys, and

those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 until the expiration of the '735 patent including any regulatory extensions;

xiii. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '735 patent;

xiv. A judgment declaring that infringement of the '735 patent is willful if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '735 patent;

xv. A judgment declaring that the '630 patent is valid and enforceable;

xvi. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202802 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 was an act of infringement of the '630 patent by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

xvii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 prior to the expiration of the '630 patent, including any regulatory extensions, will constitute an act of infringement by Actavis directly and/or indirectly, including by inducement and/or contributory

infringement;

xviii. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202802 shall be no earlier than the date on which the '630 patent expires including any regulatory extensions;

xix. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Actavis and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 until the expiration of the '630 patent including any regulatory extensions;

xx. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '630 patent;

xxi. A judgment declaring that infringement of the '630 patent is willful if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '630 patent;

xxii. A judgment declaring that the '253 patent is valid and enforceable;

xxiii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202802 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 was an act of infringement of the '253 patent by Actavis directly and/or indirectly, including by inducement

and/or contributory infringement;

xxiv. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 prior to the expiration of the '253 patent, including any regulatory extensions, will constitute an act of infringement by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

xxv. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202802 shall be no earlier than the date on which the '253 patent expires including any regulatory extensions;

xxvi. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Actavis and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 until the expiration of the '253 patent including any regulatory extensions;

xxvii. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '253 patent;

xxviii. A judgment declaring that infringement of the '253 patent is willful if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '253 patent;

xxix. A judgment declaring that the '254 patent is valid and enforceable;

xxx. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202802 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 was an act of infringement of the '254 patent by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

xxxi. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 prior to the expiration of the '254 patent, including any regulatory extensions, will constitute an act of infringement by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

xxxii. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202802 shall be no earlier than the date on which the '254 patent expires including any regulatory extensions;

xxxiii. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Actavis and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 until the expiration of the '254 patent including any regulatory extensions;

xxxiv. A judgment awarding Shire damages or other monetary relief, pursuant to 35

U.S.C. §§ 271(e)(4)(C) and 284, if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '254 patent;

xxxv. A judgment declaring that infringement of the '254 patent is willful if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '254 patent;

xxxvi. A judgment declaring that the '787 patent is valid and enforceable;

xxxvii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202802 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 was an act of infringement of the '787 patent by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

xxxviii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 prior to the expiration of the '787 patent, including any regulatory extensions, will constitute an act of infringement by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

xxxix. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202802 shall be no earlier than the date on which the '787 patent expires including any regulatory extensions;

xl. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and

permanently enjoining Actavis and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 until the expiration of the '787 patent including any regulatory extensions;

xli. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '787 patent;

xlii. A judgment declaring that infringement of the '787 patent is willful if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '787 patent;

xliii. A judgment declaring that the '030 patent is valid and enforceable;

xliv. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202802 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 was an act of infringement of the '030 patent by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

xlv. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 prior to the expiration of the '030 patent, including any regulatory extensions, will constitute an act of

infringement by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

xlvi. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202802 shall be no earlier than the date on which the '030 patent expires including any regulatory extensions;

xlvii. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Actavis and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 until the expiration of the '030 patent including any regulatory extensions;

xlviii. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '030 patent;

xlix. A judgment declaring that infringement of the '030 patent is willful if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '030 patent;

l. A judgment declaring that the '031 patent is valid and enforceable;

li. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202802 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 was an act of

infringement of the '031 patent by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

liii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 prior to the expiration of the '031 patent, including any regulatory extensions, will constitute an act of infringement by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

liii. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202802 shall be no earlier than the date on which the '031 patent expires including any regulatory extensions;

liv. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Actavis and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 until the expiration of the '031 patent including any regulatory extensions;

lv. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '031 patent;

lvi. A judgment declaring that infringement of the '031 patent is willful if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the

subject of ANDA No. 202802 that infringes the '031 patent;

lvii. A judgment declaring that the '774 patent is valid and enforceable;

lviii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202802 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 was an act of infringement of the '774 patent by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

lix. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 prior to the expiration of the '774 patent, including any regulatory extensions, will constitute an act of infringement by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

lx. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202802 shall be no earlier than the date on which the '774 patent expires including any regulatory extensions;

lxi. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Actavis and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 until the expiration of the '774 patent including any regulatory extensions;

lxii. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '774 patent;

lxiii. A judgment declaring that infringement of the '774 patent is willful if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '774 patent;

lxiv. A judgment declaring that the '770 patent is valid and enforceable;

lxv. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202802 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 was an act of infringement of the '770 patent by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

lxvi. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 prior to the expiration of the '770 patent, including any regulatory extensions, will constitute an act of infringement by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

lxvii. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202802 shall be no earlier than the date on which the '770 patent expires including any regulatory extensions;

lxviii. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Actavis and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 until the expiration of the '770 patent including any regulatory extensions;

lxix. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '770 patent;

lxx. A judgment declaring that infringement of the '770 patent is willful if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '770 patent;

lxxi. A judgment declaring that the '771 patent is valid and enforceable;

lxxii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202802 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 was an act of infringement of the '771 patent by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

lxxiii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 prior to

the expiration of the '771 patent, including any regulatory extensions, will constitute an act of infringement by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

lxxiv. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202802 shall be no earlier than the date on which the '771 patent expires including any regulatory extensions;

lxxv. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Actavis and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 until the expiration of the '771 patent including any regulatory extensions;

lxxvi. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '771 patent;

lxxvii. A judgment declaring that infringement of the '771 patent is willful if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '771 patent;

lxxviii. A judgment declaring that the '466 patent is valid and enforceable;

lxxix. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202802 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in

the United States of the product that is the subject of ANDA No. 202802 was an act of infringement of the '466 patent by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

lxxx. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 prior to the expiration of the '466 patent, including any regulatory extensions, will constitute an act of infringement by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

lxxxi. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202802 shall be no earlier than the date on which the '466 patent expires including any regulatory extensions;

lxxxii. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Actavis and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 until the expiration of the '466 patent including any regulatory extensions;

lxxxiii. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '466 patent;

lxxxiv. A judgment declaring that infringement of the '466 patent is willful if Actavis

commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '466 patent;

lxxxv. A judgment declaring that the '467 patent is valid and enforceable;

lxxxvi. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202802 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 was an act of infringement of the '467 patent by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

lxxxvii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 prior to the expiration of the '467 patent, including any regulatory extensions, will constitute an act of infringement by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

lxxxviii. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202802 shall be no earlier than the date on which the '467 patent expires including any regulatory extensions;

lxxxix. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Actavis and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 until the expiration of the '467

patent including any regulatory extensions;

xc. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '467 patent;

xci. A judgment declaring that infringement of the '467 patent is willful if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '467 patent;

xcii. A judgment declaring that the '561 patent is valid and enforceable;

xciii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202802 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 was an act of infringement of the '561 patent by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

xciv. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 prior to the expiration of the '561 patent, including any regulatory extensions, will constitute an act of infringement by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

xcv. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202802 shall be no earlier than the date

on which the '561 patent expires including any regulatory extensions;

xcvi. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Actavis and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 until the expiration of the '561 patent including any regulatory extensions;

xcvii. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '561 patent;

xcviii. A judgment declaring that infringement of the '561 patent is willful if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '561 patent;

xcix. A judgment declaring that the '619 patent is valid and enforceable;

c. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202802 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 was an act of infringement of the '619 patent by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

ci. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or

importation in the United States of the product that is the subject of ANDA No. 202802 prior to the expiration of the '619 patent, including any regulatory extensions, will constitute an act of infringement by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

cii. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202802 shall be no earlier than the date on which the '619 patent expires including any regulatory extensions;

ciii. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Actavis and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 until the expiration of the '619 patent including any regulatory extensions;

civ. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '619 patent;

cv. A judgment declaring that infringement of the '619 patent is willful if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '619 patent;

cvi. A judgment declaring that the '305 patent is valid and enforceable;

cvii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 202802 with a paragraph IV certification to

obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 was an act of infringement of the '305 patent by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

cviii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 prior to the expiration of the '305 patent, including any regulatory extensions, will constitute an act of infringement by Actavis directly and/or indirectly, including by inducement and/or contributory infringement;

cix. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 202802 shall be no earlier than the date on which the '305 patent expires including any regulatory extensions;

cx. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Actavis and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 202802 until the expiration of the '305 patent including any regulatory extensions;

cxi. A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '305 patent;

cxii. A judgment declaring that infringement of the '305 patent is willful if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 202802 that infringes the '305 patent;

cxiii. A judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Shire its attorneys' fees and costs;

cxiv. Such other and further relief as this Court may deem just and proper.

Respectfully submitted,

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